In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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DENNIS PICKENS,	*	
	*	No. 17-187V
	*	Special Master Christian J. Moran
Petitioner,	*	
v.	*	
	*	Filed: January 22, 2021
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	Entitlement, MMR vaccine,
	*	SIDP, diagnosis, ruling on the
Respondent.	*	papers
* *		

Andrew D. Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for Petitioner; Darryl R. Wishard, United States Dep't of Justice, Washington, D.C., for Respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Mr. Pickens alleges that a measles-mumps-rubella ("MMR") vaccination caused him to suffer subacute inflammatory demyelinating polyneuropathy ("SIDP"). The parties disputed when Mr. Pickens began to suffer various problems and, after a hearing during which Mr. Pickens and other witnesses testified, a ruling found facts about Mr. Pickens's health.

Each party has a retained a neurologist. Mr. Pickens relies upon the opinions of Dr. Robert Friedman. The Secretary relies upon the opinions of Dr. Peter Donofrio. They have prepared multiple reports. After these doctors

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

submitted their opinions, the parties submitted briefs in advance of a potential adjudication.

The undersigned has considered the evidence as well as the arguments. Mr. Pickens has not met his burden of establishing that he is entitled to compensation. Mr. Pickens falls short in multiple respects. He has not presented preponderant evidence that he suffers from SIDP. Even if he suffered from SIDP, Mr. Pickens has not presented a persuasive medical theory explaining how an MMR vaccine can cause SIDP. Next, Mr. Pickens has not shown that he began to suffer symptoms of SIDP within a time for which an inference of causation is appropriate. Finally, Mr. Pickens has not presented a logical sequence of cause and effect, linking his MMR vaccine to his health problems. The relative lack of persuasive evidence indicates that a hearing is not required. Consequently, this decision finds that Mr. Pickens is not entitled to compensation.

I. Background

The discussion of the events in Mr. Pickens's life is preceded by an introduction to SIDP, which occurs relatively infrequently in the Vaccine Program. This explanation of SIDP and its diagnostic criteria is intended to focus the evaluation of the events in Mr. Pickens's life.

A. SIDP

For Guillain-Barré syndrome, neuropathic problems progress for less than four weeks. For chronic inflammatory demyelinating polyneuropathy, the neuropathy progresses for more than eight weeks. Thus, cases with a progression of neuropathy over four to eight weeks could fall into a diagnostic gap. In 2003, a group of neurologists proposed an entity named "subacute inflammatory demyelinating polyneuropathy." S.J. Oh et al., *Subacute inflammatory demyelinating polyneuropathy*, 61 Neurology 1507, 1507 (2003), filed as exhibit 26. In this article, the authors reported the "the clinical, electrophysiologic, and histologic characteristics of SIDP and present[ed] the diagnostic criteria of this disorder." Id.

Oh and colleagues stated that a "definite SIDP" diagnosis was appropriate when the person met four factors. These are:

1) progressive motor and/or sensory dysfunction consistent with neuropathy in more than one limb with time to nadir between 4 and 8 weeks,

2) electrophysiologic evidence of demyelination in at least two nerves,

3) no known etiology of neuropathy other than associated diseases, and

4) no relapse on adequate follow-up.

Exhibit 26 (Oh) at 1507. Oh also recognized that "[s]upportive criteria included S1) high spinal fluid protein level of >55 mg/dL and S2) specific nerve biopsy finding of inflammatory neuropathy." Id.

In this case, both parties accepted the Oh criteria for SIDP. See Pet'r's Br. at 26; Resp't's Br. at 21. However, the parties disputed whether SIDP was an appropriate diagnosis for Mr. Pickens based upon his medical history.

B. Facts

Mr. Pickens was born on March 3, 1951. Exhibit 1 ¶ 1. People born before 1957, the Secretary argued, "are usually considered to have been infected with measles as children." Resp't's Br. at 29 (citing Centers for Disease Control and Prevention, *Epidemiology and Prevention of Vaccine-Preventable Diseases: Measles* (2015) at 12, filed as exhibit K; Patricia L. Hibberd, *Measles, mumps, and rubella immunization in adults,* UpToDate 1, 5, 8, 16-17 (2020), filed as exhibit N). Although Mr. Pickens submitted a reply, he did not address this argument.

By 2015, Mr. Pickens had retired from his job as an engineer. He lived in both Arizona and Mexico. He enjoyed activities such as motorcycling, snow skiing, snorkeling, and boating. Exhibit 37 at 4; Tr. 12-14.

On February 9, 2015, Mr. Pickens was seen by a nurse practitioner for an annual physical exam. He had no neurological or other complaints. His exam was normal, including normal strength and sensation. Exhibit 4 at 26; see also Tr. 21. He had a minimally elevated serum glucose, but his hemoglobin A1c was normal. Exhibit 4 at 44-45. On this date, he received an MMR vaccination at a Walgreen's in Chandler, Arizona. Exhibit 3 at 1; Tr. 19.

While in Mexico, Mr. Pickens started having mild numbness in his hips and buttocks on April 7, 2015. Ruling Finding Facts, issued Sept. 20, 2019, ¶ 1 (citing

evidence); see also Tr. 19, 76. The progression of numbness to weakness and pain was relatively slow. Similarly, the expansion of the problems from Mr. Pickens's hips and buttocks to his legs was also relatively slow. Ruling Finding Facts ¶ 2 (citing evidence).

On April 29, 2015, Mr. Pickens started to experience weakness (as distinct from numbness) in his lower extremities. Ruling Finding Facts ¶ 3 (citing evidence). On May 10, 2015, the pain in Mr. Pickens's hips, buttocks, and legs increased in severity. Id. ¶ 4 (citing evidence).

Mr. Pickens saw the doctor whom he usually saw on the rare occasions that he needed a doctor in Mexico, Dr. Jacobo, on or about May 12, 2015. Tr. 22, 34-35, 88. On May 14, 2015, Mr. Pickens had lab testing performed in Mexico. The results showed a normal CBC, urinalysis, metabolic panel, rheumatoid factor, C-reactive protein, and erythrocyte sedimentation rate. Exhibit 44 at 2.[2]

Mr. Pickens returned to his other home in Arizona on May 29, 2015. Tr. 38, 99, 136, 159-61. Once in Arizona, Mr. Pickens went to an urgent care in Chandler, Arizona. Exhibit 12 at 1. The intake comments state: "bilateral thigh pain/weakness, resulting in fall yesterday" and "symptoms began 4 weeks ago with hip pain." Id.; accord Tr. 100, 220. The examination revealed weak hip muscles. Exhibit 12 at 4. X-rays of the spine and hips were normal. Id. at 8.

Mr. Pickens next sought care at the Sonoran Spine Center on June 3, 2015. He reported a 20-year problem with back pain, which had worsened over the past "3-4 weeks." Exhibit 10 at 1. Mr. Pickens checked a box indicating that his symptoms were "[g]etting somewhat worse." Id. at 4. Mr. Pickens stated that the pain was severe and radiated into the buttocks and thighs. He reported the pain as burning and unlike anything he had experienced before. Due to difficulty with walking, he was using a four-wheel walker. Id.; see also Tr. 43-44, 104-08, 221.

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[2] Mr. Pickens obtained results from lab testing performed in Mexico. However, according to Dr. Jacobo, physicians do not retain copies of medical records. Tr. 174, 181, 185. In any event, Mr. Pickens did not produce records from any examination in Mexico.

At the Sonoran Spine Center, Dr. Chang saw him. On exam, Dr. Chang found that Mr. Pickens was in severe distress. His leg strength was normal with the exceptions of 4+/5 left quadriceps weakness and 4/5 bilateral hamstring weakness. His deep tendon reflexes ("DTRs") were absent at the knees and ankles bilaterally. Dr. Chang diagnosed Mr. Pickens with low back pain, and bilateral lower extremity pain and weakness. Dr. Chang started Mr. Pickens on oral corticosteroids and sent him for an MRI scan. Exhibit 10 at 12. A lumbar MRI that same day showed grade 1 spondylolisthesis (forward movement) of L3 on L4 with very mild narrowing of the neural foramina. There was no canal stenosis and no cord lesions. Id. at 6.

Two days later, on June 5, 2015, Mr. Pickens sought assistance from an orthopedist at the Hedley Orthopaedic Institute, Dr. Chow. Mr. Pickens reported that he had bilateral hip pain which had been present for two months and was getting worse. He also had pain in his thighs and calves. On exam, he had 5/5 strength in his hips, legs, and arms. Dr. Chow diagnosed bilateral hip pain, and stated that he could not rule out spinal stenosis. Exhibit 15 at 6.

Mr. Pickens returned to Sonoran Spine on June 8, 2015, and was again seen by Dr. Chang. Mr. Pickens reported no benefit from the steroids and was still walking with a four-wheeled walker. On exam, he had normal lower extremity strength with the exception of 4/5 bilateral hamstrings weakness. His upper extremity strength was normal. Dr. Chang stated that the MRI findings did not explain all symptoms, and recommended a cervical MRI, lumbar epidural injections, and physical therapy. Exhibit 10 at 10. Mr. Pickens declined the epidural. Tr. 44.

On June 10, 2015, Mr. Pickens's partner returned from their home in Mexico and saw him in distress. She brought him to the Banner University Medical Center emergency room. Tr. 163. There, Mr. Pickens complained of bilateral buttock pain radiating down both legs and lower extremity weakness, with an onset of symptoms of five weeks ago. His symptoms were worsening. Exhibit 14 at 20.

A doctor examined him in the emergency room and determined Mr. Pickens had bilateral leg weakness and diminished DTRs in his legs. The doctor admitted Mr. Pickens to the hospital. Exhibit 14 at 380.

During the hospitalization, Mr. Pickens was seen by a series of doctors, including neurologists. A neurologist, Dr. Donlon, recorded that Mr. Pickens had

4/5 weakness of his deltoids and triceps as well as 4/5 weakness of hip and knee flexion. DTRs were absent in the legs and normal in the arms. Exhibit 14 at 363 (June 11, 2015). A first-year neurology resident, Dr. Ruggle, created a list of potential diagnoses, which included Guillain-Barré syndrome ("GBS"). Id. at 359-62.

The doctors ordered multiple tests. The cerebrospinal fluid ("CSF") analysis showed an elevated protein of 218 with 24 white cells. Id. at 289. Negative (or normal) lab results included vitamin B12, creatine kinase, Lyme serology, serum protein electrophoresis, and an autoimmune panel. Id. at 283-93. Another set of normal results were MRI scans of the cervical and thoracic spine. Id. at 295 (June 12, 2015).

Based upon the test results and examination, Dr. Donlon determined that "this likely represents CIDP (versus atypical GBS presentation)." Exhibit 14 at 314. Dr. Donlon ordered plasmapheresis for five days as well as five days of IV corticosteroids. Id. On June 13, 2015, after two courses of plasmapheresis and one dose of steroids, Dr. Donlon noted 5/5 bilateral upper extremity strength and 4+/5 hip/knee flexion weakness with absent DTRs. Id. at 326.

Another neurologist, Dr. Kumar, examined Mr. Pickens on June 15, 2015. Dr. Kumar diagnosed a polyradiculoneuropathy and noted that Mr. Pickens did not meet the "8 weeks criteria of CIDP yet" but noted it was a likely possibility. Exhibit 14 at 343. Dr. Kumar again questioned whether Mr. Pickens had GBS or CIDP. Id. at 357 (June 17, 2015).

The discharge summary from June 17, 2015, reflects some uncertainty in the diagnosis. It states that Mr. Pickens's "lower extremity weakness," "pain," and "parathesias" were due to a new diagnosis of "CIDP, although atypical GBS can't be excluded." Exhibit 14 at 6. For oral testimony about Mr. Pickens's hospitalization, see Tr. 45-56, 110-19. Mr. Pickens was expected to follow up with a neurologist and physical therapist.[3]

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[3] Beginning in June 2015, Mr. Pickens often attended physical therapy. Although these notes have been reviewed, they are generally not relevant to resolving whether the MMR vaccine caused Mr. Pickens to suffer SIDP.

The neurologist, Dr. Levine, first saw Mr. Pickens on June 30, 2015. After Mr. Pickens provided Dr. Levine a history, Mr. Pickens informed Dr. Levine that he had upper and lower extremity weakness, tingling in his arms and legs, and poor coordination. In Dr. Levine's exam, Mr. Pickens had lower extremity weakness ranging from 3/5 to 4/5 proximally. His DTRs were absent in the upper and lower extremities. Dr. Levine stated that onset and progression of symptoms was consistent with GBS. Dr. Levine disagreed with Mr. Pickens's earlier diagnosis of CIDP, stating that there was no indication of recurrence or progression beyond eight weeks. Dr. Levine planned to taper Mr. Pickens's use of steroids. Dr. Levine noted that Mr. Pickens had not received the influenza vaccine in association with onset of his symptoms. Exhibit 7 at 8; see also Tr. 57-60 (Mr. Pickens's testimony about the June 30, 2015 appointment with Dr. Levine), 123-24 (same).

Dr. Levine also conducted an EMG / nerve conduction study. The EMG showed evidence of a severe motor neuropathy. Exhibit 22 at 5.

Mr. Pickens had an appointment with Dr. Andrews, who was his primary care doctor. Exhibit 4 at 23 (July 20, 2015); Tr. 69 (Mr. Pickens describing Dr. Andrews as his primary care doctor), 150 (Mr. Pickens stating that he liked Dr. Andrews). After a history and an examination, Dr. Andrews assessed Mr. Pickens as suffering from CIDP and hyperglycemia. Exhibit 4 at 24. Dr. Andrews carried forward the CIDP assessment following an appointment on August 21, 2015. Id. at 20.[4]

Yet, Dr. Levine, the neurologist, disagreed. Dr. Levine, on September 29, 2015, stated that Mr. Pickens "returns for follow up of his GBS." Exhibit 7 at 6. Dr. Levine's examination revealed "[a]reflexic" reflexes. Id. at 7. In the assessment, Dr. Levine stated "[Mr. Pickens] is recovering quite nicely from GBS. I see no evidence of ongoing disease activity to suggest CIDP." Id.

The next day, Mr. Pickens had an appointment with Dr. Andrews. Exhibit 4 at 17. In the history of present illness, Dr. Andrews recorded: "[n]europathy

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[4] Because the question to resolve after the June 11, 2019 hearing was Mr. Pickens's health between the February 2015 vaccination and the June 2015 hospitalization, Mr. Pickens was not asked questions about medical records created after July 2015.

remaining stable and better than in past." Dr. Andrews's assessment included CIDP. Id. at 18. Following this September 30, 2015 appointment with Dr. Andrews, Mr. Pickens did not seek care from a medical doctor for neurologic problems for several months. He continued to participate in formal physical therapy through March 15, 2016, when he was discharged. Exhibit 8 at 24. He noted some ongoing weakness in his right hip at discharge.

However, approximately just two weeks later, Mr. Pickens returned to physical therapy and reported that "lately" he felt weaker in his upper extremities. On exam, he was found to have 3+ to 4/5 upper extremity weakness and 3/5 right hip flexor weakness. Exhibit 8 at 20 (March 28, 2016).

On March 29, 2016, Mr. Pickens had an appointment at Phoenix Neurological. Exhibit 7 at 4. The history states that Mr. Pickens "returned to the office for followup evaluation of his Guillain-Barré syndrome." Id. Mr. Pickens complained of weakness throughout the day, but he could perform his activities of daily living. Mr. Pickens was assessed with continued weakness and the plan states: "I do not see any evidence of an active neuropathic process. I think his fatigue is most likely from his poorly treated sleep apnea . . . ." Id. at 5.

On July 11, 2016, Mr. Pickens saw Dr. Levine, reporting that his right foot still felt weak. The neurological exam was normal, and GBS was the diagnosis with no signs of recurrence. Exhibit 7 at 2.

About six months later, Mr. Pickens returned to Dr. Levine's office where he saw a nurse practitioner. NP Bland diagnosed Mr. Pickens with GBS, but stated that "based on exam I am not convinced that he is having new peripheral symptoms." Exhibit 20 at 6 (January 5, 2017). NP Bland indicated that Mr. Pickens's deficits were "most likely residual from previous illness" but scheduled an EMG to look for new signs of acute peripheral inflammation. Id.

On January 24, 2017, Mr. Pickens's bilateral lower extremity EMG was interpreted as normal, although F wave responses were noted to be absent in both peroneal nerves. Exhibit 22 at 1.

More than one year after the EMG, Mr. Pickens returned to the office of Dr. Andrews, where he saw a certified physician's assistant, Anne Sopeland, for a prescription refill. Mr. Pickens told Ms. Sopeland that he "has neuropathy that he deals with regularly and is controlled with gabapentin prescription." Exhibit 36 at

1 (January 26, 2018). He also reported "[t]ingling/[n]umbness, bilateral lower extremities, that is moderate, which is constant." Id. at 2. Under the CIDP diagnosis it is noted that "[p]atient cannot have influenza vaccine." Id. at 3.

About one month later, Mr. Pickens saw Dr. Andrews for a six-month follow up appointment. Dr. Andrews wrote that Mr. Pickens's CIDP was "fairly stable." Exhibit 36 at 6.

In anticipation of an operation to remove a squamous cell carcinoma, an anesthesiologist from the Mayo Clinic Hospital in Arizona, Dr. Frances Hu, evaluated Mr. Pickens on June 19, 2018. Mr. Pickens informed Dr. Hu that "[h]e is limited by residual peripheral neuropathy following an MMR vaccination-related [GBS] in 2015, but walks about once a week, completing approximately a mile in 20 minutes on level terrain. Intermittently uses a cane or walking stick on uneven surfaces." Exhibit 39 at 1. Dr. Hu's assessment repeats "Postvaccination [GBS]." Id. at 3.

On July 11, 2018, Mr. Pickens went to the emergency department of the Mayo Clinic Hospital in Arizona for gluteal pain. Mr. Pickens recounted that "the symptoms are similar in nature compared to when he had Guillain-Barré syndrome." Id. at 8. The emergency department doctor consulted a neurologist, Erika Driver-Dunckley.

Dr. Driver-Dunckley obtained a history going back to 2015 when Mr. Pickens had "back pain extending into the frontal thighs which [was] his presenting symptom that he had when he had his CIDP three years ago." Id. at 12. As part of this history, Mr. Pickens stated that the doctors at "Barrow's Neurological Institute" felt his condition "could be GBS, but also CIDP given the time course." Id. at 12-13. Mr. Pickens recounted that he "felt weak on his feet . . . He did try to call his primary neurologist, Dr. Levine, . . . but [he] did not have anything available for a month and a half. He then decided to come to the Emergency Department for progression of his pain and concern for return of CIDP." Id. at 13. Dr. Driver-Dunckley's summary of Mr. Pickens's past medical history included: "GBS versus CIDP in 2015, attributed to an MMR vaccination six months prior." Id. The examination revealed diminished reflexes in the bilateral Achilles. Id. at 14.

For an impression and plan, Dr. Driver-Dunckley stated, "It is interesting that the patient has the same pain presentation that he had prior to him being

diagnosed with CIDP in the past. Because he is not experiencing any weakness or progression of neurologic symptoms, we believe it is safe for the patient to be discharged home." Id. While Dr. Driver-Dunckley released Mr. Pickens from the hospital, she also encouraged a relatively quick follow up: "I did contact his primary neurologist's office and asked that he have an expedited appointment with an EMG prior to his appointment with the physician." Id.

The next day, Mr. Pickens sought assistance from staff at the Banner University Medical Center because of worsening bilateral leg pain and paresthesias over the course of two days. Exhibit 40 at 23 (July 12, 2018). Mr. Pickens informed the ER staff of his history of GBS and told the doctor "'it starts like this.'" Id. A lumbar puncture in the emergency department revealed that Mr. Pickens's CSF protein level was elevated at 122.8. Id. at 22. The admitting physician diagnosed him with radiculopathy vs. CIDP. Id. at 22-23.

While in the hospital, a neurologist consulted on Mr. Pickens's case. The neurologist diagnosed Mr. Pickens with leg paresthesias with evidence of bilateral lower extremity radiculopathy on exam as well as residual length-dependent neuropathic pain from his 2015 GBS/CIDP. The neurologist stated that CIDP was possible based on the reported urinary retention and elevated CSF protein, but noted that the presentation was atypical with preserved strength and reflexes. The consulting neurologist recommended that Mr. Pickens follow up with his regular neurologist, Dr. Levine, and obtain a repeat EMG/NCS. Id. at 207-13; see also id. at 3 (discharge summary).

Mr. Pickens returned to the Mayo Clinic for the EMG/NCS.[5] The interpreting doctor stated, "The EMG shows electrophysiologic evidence of an old neurogenic process which could reflect residue of Guillain-Barré Syndrome or less likely, a lower lumbosacral radiculopathy." Exhibit 39 at 56.

A neurologist from the Mayo Clinic saw Mr. Pickens on August 2, 2018. Mr. Pickens reported his history of GBS or CIDP and complained of "back pain." Exhibit 49 at 517, pdf 127. Mr. Pickens was found to be weak in the right hip flexor and gluteus maximus. Id. at 518. The neurologist diagnosed him with

[5] A nurse stated that Dr. Levine was out of the country. Exhibit 40 at 213.

"possible CIDP with recent exacerbation." Id. at 519. For the possible CIDP, the neurologist ordered IVIG therapy. Id. at 524.

After his last course of IVIG, Mr. Pickens returned to the Mayo Clinic and reported that he had a severe diffuse rash with blisters. Mr. Pickens thought that he had no improvement in his neurological symptoms with IVIG. His reflexes were "diffusely absent," and "sensory testing showed decreased pin sensation in the left foot and right thigh." Id. at 428. He was diagnosed with a history of GBS with a stable exam, and further IVIG was not recommended. Id. at 426-29.

In March 2019, Mr. Pickens cancelled his neurology visit and did not reschedule it. Id. at 266.

This background is the foundation for the analysis of the elements of Mr. Pickens's claim, which is set out below. In addition, the qualifications of the parties' retained experts are also relevant to the analysis of Mr. Pickens's claim.

C. Qualifications

Special masters may consider the relative expertise of testifying experts when weighing the value of their opinion. See Depena v. Sec'y of Health & Human Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), aff'd without op., 730 Fed. App'x 938 (Fed. Cir. 2018); Copenhaver v. Sec'y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016).

1. Dr. Friedman

Robert J. Friedman graduated from the University of Pittsburgh medical school in 1986. In 1987-1990, he was chief resident in neurology at the Dartmouth-Hitchcock Medical Center. In 1996, he was a clinical fellow within the department of neurology at Johns Hopkins University where he specialized in pain management. He is board-certified in neurology, pain medicine, and neuromuscular medicine. He is also certified by the American Board of Independent Medical Examiners. Exhibit 46 (curriculum vitae) at 1-2.

Since 1998, Dr. Friedman has worked in a private practice that appears to specialize in the treatment of headaches. The research studies in which he participated as a subinvestigator from 1996-1998 involved migraines. Id. at 3-4.

Dr. Friedman's curriculum vitae does not list any academic positions. He has one publication, although, as he acknowledges, he has not written "any articles published in peer-reviewed journals that inform the issues in this case." Exhibit 23 (Dr. Friedman's Dec. 20, 2017 report) at 1.

Dr. Friedman appears not to have any specialized knowledge in immunology. This apparent deficit contributes to how his opinion regarding the theory and the timing is weighed. See sections IV and V below.

2. Dr. Donofrio

Peter Donofrio received a medical degree from the Ohio State University School of Medicine in 1975. He had a residency in neurology from 1978 to 1991 at the University of Michigan Medical Center followed by a fellowship in neuromuscular medicine at the same institution. Dr. Donofrio holds board-certifications in internal medicine, neurology, electrodiagnostic medicine, and neuromuscular medicine. Exhibit B (curriculum vitae) at 1-2.

Beginning in 1981, Dr. Donofrio held various academic positions at various medical institutions. When his curriculum vitae was prepared, he was a professor of neurology and director of the neuromuscular division at the Vanderbilt University School of Medicine. Id. at 3-4. He has participated in more than 25 research programs, including some in which he was the principal investigator. Three research programs tested treatments in patients with CIDP. Id. at 9-12.

In response to an instruction asking about relevant publications, Dr. Donofrio stated that he is the author of a textbook, The Textbook of Peripheral Neuropathy, published in 2012. Exhibit A (Dr. Donofrio's April 30, 2018 report) at 1. In addition, Dr. Donofrio has written dozens of articles published in peer-reviewed journals and book chapters. His topics have included GBS and CIDP.

His work on demyelinating diseases, such as GBS and CIDP, suggests that Dr. Donofrio has some advanced knowledge in immunology because those diseases are widely considered to have an autoimmune etiology. Cf. exhibit A at 16 (listing one publication titled "Clinical Pearls from An Expert: Redefining the

Limits of Immunotherapy and Its role in Autoimmune Disease"). However, Dr. Donofrio has not stated that he is board-certified in immunology.

3. Evaluation

Dr. Friedman appears to be a competent neurologist and the undersigned does not hesitate to recognize him as an expert in the field of neurology. However, his subspecialty appears to be headaches and pain management.

Dr. Donofrio also appears to be a competent neurologist. But, his background in studying and writing about disorders of the peripheral nervous system, including GBS and CIDP, make him a better fit to opine on the issues in Mr. Pickens's case. Thus, simply by the question of qualifications, the Secretary has presented stronger evidence.

In concluding that Dr. Donofrio possesses a deeper background in the relevant topics, the undersigned has also noted a credibility issue in each of the series of reports from Dr. Friedman and Dr. Donofrio. For Dr. Friedman, there appears to be a variation in his opinion regarding the appropriate temporal relationship. Initially, Dr. Friedman stated that 6 weeks "is the approximate onset time course that has been employed to assess a link between GBS and vaccination." Exhibit 23 at 8. Later, after the Ruling Finding Facts was issued, Dr. Friedman added that because the MMR vaccine contains a live attenuated virus, "the immune response would take longer than in an inactivated vaccine (which is the type most utilized in the study of the association of GBS with seasonal influenza vaccine)." Exhibit 45 at 2. The omission of this explanation from Dr. Friedman's first report suggests that his opinion changed after the Findings of Fact.

The Findings of Fact also appear to complicate Dr. Donofrio's presentation of an opinion. After the Ruling Finding Facts was issued, the parties were directed to present the Findings of Fact with an instruction that these findings are the facts in Mr. Pickens's case. In the ensuing report, Dr. Donofrio stated, "Although I accept the facts found in this case, I would like to take the liberty to further comment on the Facts entered by Special Master Moran when compared with the facts contained in the contemporaneous medical records." Exhibit H at 1. In commenting on how he thinks the evidence preponderates after the special master has already ruled, Dr. Donofrio appears to be moving away from the perspective of a dispassionate provider of information and slipping into the role of an advocate.

The credibility issue regarding Dr. Friedman and Dr. Donofrio plays, at most, a meager role in the outcome of Mr. Pickens's case. Because the case is being adjudicated on the papers, neither Dr. Friedman nor Dr. Donofrio have been questioned about these aspects of their reports. Nonetheless, because Dr. Friedman and Dr. Donofrio appear to be qualified experts who may write reports in the future, these concerns are noted here with the hope that they will not be repeated.

II. Standards for Adjudication

A petitioner is required to establish his case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (Fed. Cir. 2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

III. Diagnosis

In Broekelschen v. Sec'y of Health and Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence presented in the record before applying the Althen test." Citing Broekelschen, the Federal Circuit has also explained that "[i]n the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

Here, the parties disagree about the appropriate diagnosis. Mr. Pickens's expert, Dr. Friedman, states that Mr. Pickens suffered from subacute inflammatory demyelinating polyneuropathy ("SIDP"). Exhibit 23 at 8; accord exhibit 45 at 2.

In contrast, the Secretary's expert in neurology, Dr. Donofrio, disagrees. He stated that Mr. Pickens does not suffer from SIDP. (Dr. Donofrio also states that Mr. Pickens does not suffer from GBS or CIDP.) Exhibit A at 8.

As mentioned earlier, the parties agree that the Oh article sets forth the relevant diagnostic criteria for SIDP. See exhibit 26. The parties agree that of the four criteria, Mr. Pickens satisfies one criterion---no other etiology for his neurologic problems. The remaining three criteria are discussed below. These are: a progressive motor and/or sensory dysfunction in more than one limb with time to nadir 4-8 weeks, electrophysiologic evidence of demyelination in at least two nerves, and no relapse on adequate follow up.

a progressive motor and/or sensory dysfunction in more than one limb with time to nadir 4-8 weeks

Mr. Pickens started having mild numbness in his hips and buttocks on April 7, 2015. Ruling Finding Facts ¶ 1. The parties accept this development as the beginning of Mr. Pickens's neurologic problems. The question becomes did Mr. Pickens reach his nadir four to eight weeks later?

In Mr. Pickens's brief, he argues that "May 29, 2015 is a strong contender for the date of nadir." Pet'r's Br. at 36. Dr. Friedman more generally opines that "the progression of Mr. Pickens' peripheral nerve condition was compatible with an approximately 4-8 week time period of progression." Exhibit 45 at 2. Dr. Friedman, however, did not identify May 29, 2015 as the nadir. May 29, 2015 is 52 days (or nearly eight weeks) after April 7, 2015.

Counsel's selection of May 29, 2015 as the nadir is unpersuasive. While Mr. Pickens did seek medical attention at an urgent care center, see exhibit 12 at 1, his symptoms progressed after that date. Just a few days later, Mr. Pickens checked a box saying his symptoms were "[g]etting somewhat worse." Exhibit 10 at 1 (June 3, 2015). Two more days later, Mr. Pickens told Dr. Chow, an orthopedist at the Hedley Orthopaedic Institute, that he was getting worse. Exhibit 15 at 6, cited in Resp't's Br. at 5. It appears that Mr. Pickens continued to decline until his partner returned from Mexico on June 10, 2015. When she saw his degree

of distress, she brought him to the emergency room. In the emergency room, Mr. Pickens again said that he was worsening. Exhibit 14 at 20. Neither Mr. Pickens's attorney nor Dr. Friedman specifically discuss these medical records after May 29, 2015.

This series of medical records pushes Mr. Pickens's nadir to June 10, 2015. A progression of symptoms from April 7, 2015, to June 10, 2015, amounts to a course that is 64 days, approximately nine weeks. Thus, this duration does not fit the diagnostic criteria for SIDP.

electrophysiologic evidence of demyelination in at least two nerves

The parties dispute whether Mr. Pickens fulfills this criterion with any of the three EMG/NCS tests he underwent. These tests were performed on June 30, 2015 (exhibit 22 at 5), January 24, 2017 (exhibit 22 at 1-4), and July 28, 2018 (exhibit 39 at 56-58).[6] Mr. Pickens relies most heavily on the June 30, 2015 test. See Pet'r's Br. at 22.

The results of June 30, 2015 test, which Dr. Levine ordered, show various measurements without any notation as to whether the results were expected or abnormal. Exhibit 22 at 5. But, the entirety of the "summary/interpretation" is "[t]his study found evidence for a severe motor neuropathy." Id.

Dr. Donofrio stated that this study showed "minimal changes . . . not severe enough to classify as demyelinating." Exhibit P at 1. However, Dr. Donofrio does not explain the basis for his reasoning that the changes were minimal.

The evidence on this narrow point is relatively close. Dr. Donofrio is correct that Dr. Levine's interpretation of the June 30, 2015 test does not literally say "demyelinating." On the other hand, the interpretation does say a "severe motor neuropathy," leaving open the possibility that Mr. Pickens's injury was demyelinating. The results of the third EMG/NCS, which was administered on

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[6] The earliest of these tests was performed 20 days after Mr. Pickens reached nadir. The next two tests were performed approximately 18 months and approximately two years later. Neither expert discussed how the passage of time affects the value of the diagnostic tests, if at all.

July 24, 2018, elevates this possibility to a probability. The interpretation of this study was that the results showed "evidence of an old neurogenic process which could reflect residua of Guillain-Barré Syndrome." As Mr. Pickens argued, GBS is a demyelinating disease. See Pet'r's Reply at 4. Thus, taken as a whole, the evidence preponderates, even if slightly, in favor of finding that Mr. Pickens met this criterion.

no relapse on adequate follow up

The remaining criterion concerns any relapse. This criterion helps distinguish SIDP from chronic inflammatory demyelinating polyneuropathy. See Pet'r's Br. at 27 n.3 (suggesting that if Mr. Pickens did have a relapse, then CIDP was an appropriate diagnosis).

Mr. Pickens may have suffered a relapse in symptoms in January 2017 and July 2018. First, on January 5, 2017, Mr. Pickens was seen by nurse practitioner Bland in the office of Dr. Levine. Mr. Pickens complained about "increased LE/LBP and numbness in thighs for the last couple of weeks." Exhibit 20 at 5. However, NP Bland concluded that the deficits were "most likely residual from previous illness." Id. at 6. Moreover, the January 24, 2017 EMG/NCS was normal. See exhibit 22 at 1-4; exhibit P (Dr. Donofrio's report describing the results as "normal").

Second, and more importantly, Mr. Pickens's treatment at the Mayo Clinic in July-October 2018 constitutes a relapse according to Dr. Donofrio. Exhibit P at 1. Mr. Pickens told both the emergency room doctor and Dr. Driver-Dunckley, a neurologist, that his symptoms were similar to the symptoms he experienced in 2015. Exhibit 39 at 8, 12. Mr. Pickens communicated similar information to a doctor at the Banner University Medical Center. Exhibit 40 at 23 (reporting "it starts like this"). A neurologist who examined Mr. Pickens on August 2, 2018, diagnosed him with "possible CIDP with recent exacerbation." Exhibit 49 at 519. Against these reports, Mr. Pickens argues that he did not relapse because he did not respond to IVIG. Pet'r's Reply at 3 (citing exhibit 49 at 428-29). However, people with CIDP or other demyelinating diseases do not always respond to IVIG. Thus, the lack of response does not undermine Dr. Donofrio's opinion that Mr. Pickens suffered a relapse in 2018.

In sum, of the four diagnostic criteria, Mr. Pickens definitely meets one (no other etiology). He probably meets another criterion, electrophysiologic evidence

of demyelination. But, he does not meet the other two criteria, a progression to nadir in four to eight weeks and no relapse.

In addition to considering how Dr. Friedman and Dr. Donofrio have evaluated Mr. Pickens in light of the criteria, the undersigned has also considered the views of treating doctors. The diagnoses of treating doctors can be valuable because they have first-hand experience in examining their patients and they are usually presenting opinions outside the context of litigation. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Here, the Secretary argued that no treating doctor diagnosed Mr. Pickens as suffering from SIDP. Resp't's Br. at 23. Although Mr. Pickens filed a reply, he did not rebut this argument and the undersigned has not located any treaters who diagnosed Mr. Pickens with SIDP.

For these reasons, Mr. Pickens has failed to establish that he suffers from SIDP.

IV. Theory

Assuming that Mr. Pickens had established that he suffered from SIDP, his burden includes presenting evidence regarding "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. The theory must be probable, not just possible. Boatmon v. Sec'y of Health & Human Servs., 941 F.3d 1351, 1360 (Fed. Cir. 2019).

Here, in his brief, Mr. Pickens has advanced "molecular mimicry." Pet'r's Br. at 27. This assertion, in turn, rests upon Dr. Friedman's opinions. In his first report, Dr. Friedman maintains that "[v]accines that contain antigens from infectious agents may induce autoimmune events by several mechanisms such as molecular mimicry, epitope spreading, bystander activation, and polyclonal activation." Exhibit 23 at 7 (citing Nancy Agmon-Levin et al., *Vaccines and autoimmunity*, 5 Nat. Rev. Rheumatol. 648, 648-52 (2009), filed as exhibit 28). Other than this sentence, the term "molecular mimicry" does not appear in Dr. Friedman's first report. The term also does not appear in Dr. Friedman's second report.

By citing cases, Mr. Pickens argues that special masters have accepted molecular mimicry. Pet'r's Br. at 27-28 n.4. However, the Secretary countered "merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does

not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question." Resp't's Br. at 23-24 (quoting McKown v. Sec'y of Health & Human Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019)). McKown's description of the burden seems to fit the appellate guidance. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 135 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012).

Here, the evidence does not support a finding that molecular mimicry can explain how an MMR vaccine can cause SIDP. The primary evidence, Dr. Friedman's report, is conclusory. It does not propose any homologies between components of the MMR vaccine and any human tissue involved in the pathogenesis of SIDP. As such, Dr. Friedman's report is one of the thinnest opinions regarding molecular mimicry.

Admittedly, Dr. Friedman cites some literature that he contends supports his hypothesis that the MMR vaccine can cause SIDP via molecular mimicry.[7] Preliminarily, none of the articles address SIDP specifically. Instead, the articles discuss a more common demyelinating condition, GBS. Because Dr. Friedman has explained that SIDP represents a condition between GBS and CIDP, an extrapolation from articles about GBS to SIDP seems reasonable, at least when the Secretary has not objected. However, these articles do not show that the MMR vaccine can cause GBS.

The strongest evidence weighing against the finding that the MMR vaccine can cause GBS is a set of epidemiological studies. For a lengthy discussion of how epidemiologic studies contribute to an analysis of causation in the Vaccine Program, see Tullio v. Sec'y of Health & Human Servs., No. 15-51V, 2019 WL 7580149, at *5-11 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), mot. for rev. denied, 149 Fed. Cl. 448 (2020). In the first study, researchers compared the incidence of GBS among approximately 73 million children living in Argentina, Brazil, Chile, and Colombia between 1990 and 1994, who received a measles vaccine during a mass vaccination campaign. The authors concluded, "We found no evidence of a relation between measles vaccination and GBS." Claudio da Silveria et al.,

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[7] The Secretary skipped any discussion of the articles on which Dr. Friedman relied. See Resp't's Br. at 24.

Measles vaccination and Guillain-Barré syndrome, 349 Lancet 14, 16 (1997), filed as exhibit 33.

The second study considered people hospitalized for GBS in Finland from 1982 to 1986, during which more than a half-million people received an MMR vaccine. The researchers detected no increase in the cases of GBS. Thus, they concluded that their study "provides further evidence against the postulated causal relation between MMR vaccination and GBS." Annamari Patja et al., *Risk of Guillain-Barré syndrome after measles-mumps-rubella vaccination*, 138 J. Pediatrics 250, 253 (2001), filed as exhibit 34.

To Dr. Friedman's credit, he cited these population-based studies. However, Dr. Friedman does not persuasively argue against them. See exhibit 23 at 8.

The presence of two large epidemiologic studies weighs against the finding of causation. However, epidemiology is not the only factor that contributes to an evaluation of prong 1. Thus, the remaining articles Dr. Friedman cites are considered as well.

Dr. Friedman cited the package insert for the vaccine. Exhibit 23 at 7. The manufacturer listed "adverse reactions . . . without regard to causality . . . [that] have been reported during clinical trials." Exhibit 30 at 6. One of those conditions was "Guillain-Barré syndrome." Id. at 7. Guillain-Barré syndrome is not listed in the sections of the product insert listing "contraindications," "warnings," and "precautions." Id. at 3-7.

When the manufacturer's statements about potential vaccine causation do not stem from a scientific exploration of causation, special masters have not given manufacturers' package inserts much weight. In a leading case, one special master went so far as to declare that "federal regulations specifically preclude the contents of drug product labels, as reproduced in the [Physician's Desk Reference], from serving as admissions regarding causation." Werderitsch v. Sec'y of Health & Human Servs., No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005). Relying upon regulations found at 21 C.F.R. § 600.80, Werderitsch reasoned that because the Food and Drug Administration requires manufacturers to list adverse occurrences regardless of causality, the listing of an event on a product insert does not support a finding of causation. Other cases declining to rely upon package inserts to support a finding of causation include: Salerno v. Sec'y of Health & Human Servs., No. 16-1280, 2020 WL 344163, at *13 (Fed. Cl. Spec.

Mstr. May 29, 2020); Bender v. Sec'y of Health & Human Servs., No. 11-693V, 2018 WL 3679637, at *31 (Fed. Cl. Spec. Mstr. July 2, 2018) (noting that "vaccine package inserts do not constitute causation evidence meriting significant weight"), mot. for rev. denied, 141 Fed. Cl. 262 (2019); Tompkins v. Sec'y of Health & Human Servs., No. 10-261V, 2013 WL 3498652, at *14 (Fed. Cl. Spec. Mstr. June 21, 2013) (citing the testimony of petitioner's expert who acknowledged that reports in package inserts "may reflect a temporal relationship between vaccine and illness"), mot. for rev. denied, 117 Fed. Cl. 713 (2014); Coppola v. Sec'y of Health & Human Servs., No. 09-631V, 2012 WL 1118849, at *26 (Fed. Cl. Spec. Mstr. Mar. 7, 2012) (rejecting a petitioner's reliance on vaccine package insert information as indicative of alleged vaccine causation); Doe v. Sec'y of Health & Human Servs., No. 99-670V, 2004 WL 3321302, at *14 (Fed. Cl. Spec. Mstr. Oct. 5, 2004) (finding that petitioner failed to establish that hepatitis B vaccine can cause chronic fatigue syndrome although the package insert listed several symptoms petitioner experienced). But see Russell v. Sec'y of Health & Human Servs., No. 11-0282V, 2014 WL 4922194, at *7 (Fed. Cl. Spec. Mstr. Sept. 9, 2014) (giving some weight to a manufacturer's report of an adverse event "judged to be vaccine related by the study investigator" but still finding that petitioner failed to meet the burden regarding prong 1). Here, the manufacturer's report that Guillain-Barré syndrome has occurred during clinical trials was stated "without regard to causality." Exhibit 30 at 6. In accord with these non-binding precedents, the undersigned declines to give the manufacturer's insert more weight than the epidemiologic studies.

So, too, the epidemiologic studies carry more weight than the two case reports Dr. Friedman cites. These case reports are exhibit 31 (Morris) and exhibit 32 (Atkins). In general, case reports provide little, if any, information helpful to determining causation because they present only a temporal sequence of events in which the vaccination preceded an adverse health event. See K.O. v. Sec'y of Health & Human Servs., No. 13-472V, 2016 WL 7634491, at *11-12 (Fed. Cl. Spec. Mstr. July 7, 2016) (discussing appellate precedent on case reports).

Finally, Dr. Friedman also cites a study based upon the Vaccine Adverse Events Reporting System ("VAERS") database. Nizar Souayah et al., *Guillain-Barré syndrome after vaccination in the United States A report from the CDC/FDA Vaccine Adverse Event Reporting System*, 25 Vaccine 5253 (2007), filed as exhibit 25. One special master declined to rely upon this article because it lacked an unvaccinated population who can serve as a comparison group. See Tompkins,

2013 WL 3498652, at *26 n.66. Moreover, even if the methodology of the Souayah researchers could be set aside, the findings of the Souayah group with respect to the MMR vaccine are ambiguous. The entirety of their discussion of the MMR vaccine is contained in a single sentence: "Although no report of GBS following measles–mumps–rubella vaccine (MMR) was observed in our study, it was the most frequent vaccine associated with GBS when administrated with other vaccines (6 patients)." Exhibit 25 (Souayah) at 5255. The presence of another vaccine confounds any attempt to draw a meaningful conclusion about the MMR vaccine.

For these reasons, Mr. Pickens has not established that molecular mimicry is a persuasive medical theory to explain how the MMR vaccine can cause GBS. It, therefore, follows that this theory cannot be extended as a basis for finding that the MMR vaccine can cause SIDP, the condition from which Dr. Friedman asserts that Mr. Pickens suffers. Consequently, Mr. Pickens has not met his burden regarding prong 1.

V. Timing

Assuming that Mr. Pickens had established the condition for which he sought compensation and further assuming that Mr. Pickens had established that molecular mimicry persuasively explained how the MMR vaccine can cause SIDP, Mr. Pickens would also be required to present preponderant evidence regarding timing. As discussed above, Mr. Pickens has not met his burden regarding diagnosis or theory. Nevertheless, for sake of completeness, the timing prong is discussed as well.

"[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and that the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013). Because the onset of Mr. Pickens's alleged SIDP is less controversial, the analysis begins with that issue.

A. Onset of Neurologic Problems

Mr. Pickens started having mild numbness in his hips and buttocks on April 7, 2015. Ruling Finding Facts ¶ 1 (citing evidence). The spread of his problems to his legs was relatively slow. Id. (citing evidence). On April 29, 2015, Mr. Pickens started to experience weakness (as distinct from numbness) in his lower extremities. Id. ¶ 3 (citing evidence).

Which of these problems constituted a manifestation of SIDP is not entirely clear. As noted in the Order for Submissions in Advance of Potential Adjudication, "the experts' responses to the Ruling were cursory. Dr. Friedman did not identify what problem was the initial manifestation of SIDP, although he stated the time course was still consistent. Exhibit 45 at 2. Dr. Donofrio, similarly, did not state what symptom was an initial manifestation of SIDP perhaps, because Dr. Donofrio does not agree with the SIDP diagnosis. Dr. Donofrio did note that the earliest symptom, mild numbness in the hips and back, began 57 days after the vaccination." Order, issued Apr. 27, 2020, at 6.

Mr. Pickens argues that April 7, 2015, marks the onset of Mr. Pickens's SIDP. Pet'r's Br. at 35. As an attorney's argument, the selection of this date is fair. While Mr. Pickens's case would be stronger if Dr. Friedman directly offered an opinion as to what problem marked a manifestation of SIDP, the Secretary did not forcibly challenge April 7, 2015, as the starting point for the alleged SIDP. See Resp't's Br. at 26-27. Thus, for the sake of argument, the undersigned assumes that April 7, 2015, is the beginning of Mr. Pickens's neurologic condition. April 7, 2015, is 57 days (approximately eight weeks) after the February 9, 2015 vaccination. The ensuing and more controverted point is whether 57 days is an amount of time for which an inference of causation is appropriate.

B. Appropriate Temporal Relationship

Analogizing to GBS, Dr. Friedman proposed that an acceptable interval is six weeks. Exhibit 23 at 8; see also 42 C.F.R. § 100.3 ¶ XIV.D (associating flu vaccine with GBS that develops within 3-42 days). Six weeks was used in the epidemiologic studies. See exhibit 33 (da Silveria) at 14; exhibit 34 (Patja) at 250. Later, Dr. Friedman stated that the latency after an MMR vaccine would be longer because the MMR vaccine contains a live attenuated virus. Exhibit 45 at 2. The entirety of Dr. Friedman's report on this point is:

> Given the nature of the MMR vaccine (a live attenuated vaccine), the immune response would take longer than in an inactivated vaccine (which is the type most utilized in the study of the association of GBS with seasonal influenza vaccine). Additionally, the latency between immune exposure and a more subacute onset condition such as SIDP would be longer than that expected with GBS. For these reasons additionally, the time course of the onset of Mr. Pickens' SIDP condition was still consistent with the immune response to the MMR vaccine being a significant contributing factor to Mr. Pickens' SIDP condition.

Id. This discussion from an expert is unusually brief.

As Dr. Friedman suggested, the MMR vaccine contains a live attenuated virus. Mr. Pickens builds on this statement, adding that "the MMR vaccination takes time to replicate in the body before it induces an immune response." Pet'r's Br. at 34. One basis is a statement from the CDC. Centers for Disease Control and Prevention, *Principles of Vaccination* (last reviewed Nov. 15, 2016) at 6, filed as exhibit 29 ("To produce an immune response, live attenuated vaccines must replicate (grow) in the vaccinated person. A relatively small dose of virus or bacteria is administered, which replicates in the body and creates enough of the organism to stimulate an immune response."). Another basis is Ahlum v. Sec'y of Health & Human Servs., No. 12-763V, 2018 WL 4323623 (Fed. Cl. Spec. Mstr. Aug. 16, 2018).

In response, the Secretary challenges the extension beyond 42 days. Relying upon an article published by the Centers for Disease Control and Prevention covering the epidemiological aspects of the measles virus, the Secretary asserts that the immune response to the measles vaccination develops within 7-9 days. Resp't's Br. at 28 (citing exhibit K at 1-2, 14). The Secretary further notes that the Vaccine Injury Table lists certain injuries as associated with an MMR vaccine, but the timeframes are 42 days or less. For thrombocytopenic purpura after measles vaccine (included as part of the MMR vaccine), see 42 C.F.R. § 100.3 ¶ V.A (5-30 days). For encephalopathy after MMR, see 42 C.F.R. § 100.3 ¶ III.B (5-15 days). For chronic arthritis after rubella vaccine (included as part of the MMR vaccine), see 42 C.F.R. § 100.3 ¶ IV.A (7-42 days). Finally, the Secretary contends that because Mr. Pickens suffered a measles infection as a child, his exposure to the MMR vaccine should have generated a more rapid response due to memory cells. Resp't's Br. at 29.

Overall, the experts' reports on this issue were limp. As noted in the discussion of Dr. Friedman's and Dr. Donofrio's qualifications, neither doctor appears to have any particular knowledge of the immune system. The consequence of this relative weakness in the expert's background falls more heavily on Mr. Pickens because he, as the petitioner, bears the burden of presenting a persuasive case. Dean v. Sec'y of Health & Human Servs., No. 13-808V, 2017 WL 2926605, at *18 n.12 (Fed. Cl. Spec. Mstr. June 9, 2017). And, this persuasive case must be made through "medical records or medical opinion." 42 U.S.C. § 300aa–13(a)(1).

However, the record includes medical literature and the attorneys have constructed arguments based upon those exhibits. While attorney argument does not constitute evidence, the undersigned has considered the medical literature and arguments from both Mr. Pickens and the Secretary.

Tentatively, the undersigned is inclined to find that Mr. Pickens has not met his burden of establishing that 57 days is within an appropriate period to establish causation. First, when researchers explored whether the MMR vaccine increased the incidence of GBS after vaccination, the researchers used 42 days as their period. Exhibit 33 (da Silveria) at 14. This selection suggests that 42 days remains an outside limit for an MMR vaccine-induced demyelinating injury.

Second, while Dr. Friedman states that an immune response to a vaccine containing a live yet attenuated virus "would take longer" than the immune response to a vaccine containing an inactivated pathogen, Dr. Friedman did not quantify how much longer. This vagueness in Dr. Friedman's opinion is a deficiency. Dr. Friedman did not address or account for information suggesting that the immune response to the MMR vaccine happens within 7-9 days. If, simply for sake of argument, 9 days is added to 42 days, then the result is 51 days.

Third, the Secretary's point about a memory response predicting a quicker response could be valid. But, the Secretary's response itself has holes. The Secretary relies upon Mr. Pickens's exposure to the measles virus in childhood. But, what about mumps and rubella? If either the mumps portion or the rubella portion of the MMR vaccine were responsible for the molecular mimicry (for which there is no evidence), then Mr. Pickens's encounter with these pathogens through the vaccination might be his first.

The undersigned could conduct a hearing to receive oral testimony from Dr. Friedman and Dr. Donofrio on these questions. However, in an exercise of

discretion, the undersigned declines to hold a hearing. Both parties were informed that the expert reports could constitute direct testimony and that a hearing might not be held. Order Regarding Expert Reports, issued Oct. 13, 2017, at 1-2. With this awareness, the parties produced these reports. It seems reasonable to infer that if Dr. Friedman and/or Dr. Donofrio were capable of saying more, they would have expressed those opinions in writing. See Sphan v. Sec'y of Health & Human Servs., 133 Fed. Cl. 588, 601 (2017) (noting that special master reasonably determined that a hearing was not required after parties developed an extensive evidentiary record).

More importantly, the outcome on timing does not affect the outcome of this case. Even if Mr. Pickens had established that his problem began within a time for which an inference of causation is appropriate, this showing would not carry the day for him. See Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Mr. Pickens is also required to show (1) that he suffers from SIDP and (2) that molecular mimicry is a persuasive theory to connect the MMR vaccine and SIDP. Mr. Pickens has not met his burden on either aspect. Thus, a hearing and a finding on prong 3 favorable to Mr. Pickens would be academic.

VI. Logical Sequence

Mr. Pickens's final element to establish is "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. Given that Mr. Pickens did not establish that he suffers from the condition for which he seeks compensation and did not present a persuasive medical theory explaining how the MMR vaccine can cause SIDP, it also follows as a matter of logic that Mr. Pickens has not presented a logical sequence of cause and effect. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 145 (2011), aff'd without op., 463 F. App'x 932 (Fed. Cir. 2012). However, this element is summarily discussed further for the sake of completeness.

With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). In this case, although directed to present any helpful statements from treating doctors, Order for Submissions in Advance of Potential Adjudication, issued Apr. 27, 2020, at 5, Mr. Pickens has not. See Pet'r's Br. at 30; see also Resp't's Br. at 26 (asserting "SIDP

was never diagnosed by any of [Mr. Pickens's] medical providers"). This lack of support from treaters does not assist Mr. Pickens in meeting his burden.

Rather, Mr. Pickens asserts that no other cause for his problem has been identified. However, the Federal Circuit has disagreed with the proposition that the lack of alternative cause means that the vaccination was the cause. See Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1320-21 (Fed. Cir. 2010).

In this context, the views of the doctors who suggested that Mr. Pickens suffered from either GBS or CIDP have been considered. As discussed in the summary of events in Mr. Pickens's life, doctors who treated him did not diagnose Mr. Pickens with the same disease consistently. Some suggested that he might have GBS. E.g., exhibit 14 at 359-62, 6 (discharge report), exhibit 7 at 6, exhibit 39 at 12, 56. Others stated that he might have CIDP. E.g., exhibit 14 at 314, 6 (discharge report), exhibit 4 at 24, exhibit 39 at 12. However, none of the doctors stated that Mr. Pickens suffered from SIDP and none of the doctors persuasively linked Mr. Pickens's health problems to the MMR vaccination.[8] In any event, Mr. Pickens has not asserted a claim based upon him suffering from GBS or CIDP. See Pet'r's Br. at 25 ("Mr. Pickens suffers from Subacute Inflammatory Demyelinating Polyneuropathy."). Likewise, Dr. Friedman has not presented an opinion that the MMR vaccine caused Mr. Pickens to suffer GBS or CIDP. See exhibit 23 at 8 ("SIDP best explains the apparent progression of the neurological deficits from the disease over 4 to 8 weeks."); exhibit 45. Special masters are not required to evaluate claims that the parties have not advanced. See Vaccine Rule 8(f).

Consequently, Mr. Pickens has not met his burden of proof regarding prong 2.

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[8] Perhaps the most supportive statement is a line from an anesthesiologist, Dr. Hu, who seems to have adopted the history that Mr. Pickens gave him. Exhibit 39 at 1 (report, dated June 19, 2018). But, Dr. Hu does not explain the basis for his assessment about Mr. Pickens's condition three years earlier.

VII. A Hearing is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Human Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018). Here, after considering the entire record as well as the parties' arguments, the undersigned has determined that a hearing is not required.

First, Mr. Pickens has enjoyed an opportunity to present his case fairly and fully. After the parties disputed the onset of Mr. Pickens's problems, the undersigned conducted a hearing to receive testimony from Mr. Pickens and any others whom he wanted to call as witnesses. After the undersigned issued the Ruling Finding Facts, the parties were permitted to submit additional expert reports. Then, the undersigned issued an order, scheduling the submission of briefs in advance of potential adjudication. This order allowed the parties yet another opportunity to present reports from experts. Thus, the undersigned finds that Mr. Pickens has had a reasonable opportunity to present his case.

Second, the evidence that Mr. Pickens has presented is not persuasive. The lack of persuasiveness is particularly apparent with respect to Mr. Pickens's diagnosis and medical theory. On diagnosis, little credible evidence suggests that Mr. Pickens suffers from SIDP according to the diagnostic criteria. Dr. Friedman could have addressed Mr. Pickens's nadir, including his medical records created after May 29, 2015, in his written reports. Similarly, Dr. Friedman could have addressed Mr. Pickens's health in 2018, when he apparently suffered a relapse in his neurologic problems in a report filed in conjunction with Mr. Pickens's brief. Most importantly, any testimony from Dr. Friedman would not change the fact that no treating doctor diagnosed Mr. Pickens as suffering from SIDP. As for molecular mimicry, Mr. Pickens falls well short of presenting what could amount to a persuasive showing. These independent reasons are sufficient to find, without a hearing, that Mr. Pickens is not entitled to compensation.

As explained above, Mr. Pickens has a slightly stronger claim that he meets the third prong concerning timing. But, on this point, Mr. Pickens's evidence seems not to rise to the level of more-likely-than-not. And, even if Mr. Pickens were to prevail on timing, he would remain not eligible for compensation due to the deficiencies on diagnosis and prong 1.

VIII. Conclusion

Mr. Pickens has not established that he suffered from SIDP and has not established that the MMR vaccine can cause SIDP via molecular mimicry. Due to Mr. Pickens's failure to meet his burden, he is not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

IT IS SO ORDERD.

S/ Christian J. Moran
Christian J. Moran
Special Master